K003561

APR 1 7 2001

510(k) SUMMARY

Invacare Corporation's
Invacare Passover Humidifier
Model ISP9700

Submitter's Name, Address, Telephone Number
Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Contact Person:
Rae Ann Farrow
Manager, Regulatory Compliance

Date Prepared: November 13, 2000

Name of Device and Name/Address of Sponsor
Invacare Passover Humidifier

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Common or Usual Name
Passover Humidifier

Classification Name
Humidifier, Respiratory Gas (Direct Patient Interface)

Predicate Devices
Resmed Sullivan Passover Humidifier (K950582)
Puritan-Bennett Passover Humidifier (K936000)
Respironics Passover Humidifier (K945782)

Intended Use
The Invacare ISP9700 Passover Humidifier is a non-electrically powered device that is used in conjunction with a Continuous Positive Airway Pressure (CPAP) or a Bi-level CPAP device. It's intended use is to minimize dryness in the nose and throat of CPAP/Bi-level CPAP patients by adding moisture to the inspired air.

Technological Characteristics and Substantial Equivalence

Device Description
The Invacare ISP9700 Passover Humidifier is a non-electrically powered device that is used in conjunction with a Continuous Positive Airway Pressure (CPAP) or a Bi-level CPAP device. It's intended use is to minimize dryness in the nose and throat of CPAP/Bi-level CPAP patients by adding moisture to the inspired air.

The Invacare Passover Humidifier is a container that is partially filled with water and placed beneath the flow generator. The unit increases the relative humidity of the air stream being supplied to the end user. The passover humidifier redirects the air from the flow generator over the water in the humidifier. As the air passes over the surface of the water, the air absorbs vapor moisture by evaporation, increasing the amount of moisture in the inspired air. The humidified air helps to relieve the discomfort caused by the dry pressurized air. The unit is not a heated humidifier.

The passover humidifier consists of a blow molded plastic container and a reusable flexible tube that connects the humidifier to the flow generator. It has two ports. Both ports can be used to fill the unit with distilled or demineralized water. Either port can be use to connect the flexible tubing from the humidifier to the flow generator. The other port connects to longer tubing, which in turn connects to the end user by way of the patient interface (i.e. mask).

The container is made from a translucent polycarbonate plastic. This allows the end user to view the water level in comparison to the fill line. The humidifier is to be filled only when disconnected from the flow generator. The liquid in the humidifier will not enter any other part of the patient circuit when the device is operating on surface tilted up to 5°. The air outlets on the unit are elevated to prevent water from spilling into the connection system from the humidifier to the patient mask.

The humidifier will be sold with the Invacare Polaris CPAP unit as well as being sold individually. The Invacare Passover Humidifier can be used with standard CPAP devices from other manufacturers, which have maximum operating pressures of 20 cm H_20 and do not have automatic pressure titration capabilities.

On a daily basis, the humidifier and tubing should be cleaned with mild detergent. On a weekly basis, the humidifier should be soaked in a combination of disinfectant solution and cold water for 30 minutes.

Substantial Equivalence

The Invacare Passover Humidifier is substantially equivalent to the following devices:

- Resmed Sullivan Passover Humidifier (K950582)
- Puritan-Bennett Passover Humidifier (K936000)
- Respironics Passover Humidifier (K945782)

Performance Data

The Invacare Passover humidifier was tested in accordance with the mechanical and environmental performance requirements for home use respiratory devices set forth in the Anesthesiology and Respiratory Devices Branch's November 1993 document entitled "Reviewer Guidance for Premarket Notification Submissions ", published by the Anesthesiology and Respiratory Devices Branch. In all instances the device met the required performance criteria and functioned as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 7 2001

Ms. Rae Ann Farrow
Invacare Corporation
899 Cleveland Street
P.O. Box 4028
Elyria, OH 44036-2125

Re: K003561
Invacare Model ISP9700/Passover Humidifier
Regulatory Class: II (two)
Product Code: 73 BTT
Dated: March 20, 2001
Received: March 21, 2001

Dear Ms. Farrow:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~TBD~~ K003561

Device Name: *Invacare Model ISP9700/Passover Humidifier*

Indications For Use:

It's intended use is to minimize dryness in the nose and throat of CAP/BI-level CPAP patients by adding moisture to the inspired air.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003561

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)